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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,773	09/27/2000	Clark Pan	MSB-7272	7437

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EXAMINER
MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	4

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/671,773	PAN ET AL.	
	Examiner	Art Unit	
	Marjorie Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Compy* .

Election/R strictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 6-19, drawn to a polypeptide and pharmaceutical compositions comprising the polypeptide, classified in class 530, subclass 300.

II. Claims 2-4, drawn to a polynucleotide, classified in class 536, subclass 23.5.

III. Claim 5, drawn to a method of producing a polypeptide, classified in class 435, subclass 69.1.

IV. Claim 20, drawn to an antibody, classified in class 530, subclass 387.9.

V. Claims 21-28, drawn to a method of treatment using a PACAP R3 agonist, classified in class 514, subclass 2.

VI. Claim 29, drawn to a peptide of defined structure, classified in class 530, subclass 300.

VII. Claim 30, drawn to a method to stimulate insulin release using a peptide, classified in class 514, subclass 2.

VIII. Claim 31, drawn to a method to treat a respiratory disorder using a polypeptide, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Group II is separate and distinct from Groups I, III, and V-VIII because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups 1, III, and V-VIII the critical feature is a polypeptide whereas for Group II the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group I to be directed as to its synthesis by a polynucleotide of Group II, however, the completely separate chemical types of the inventions of Groups I and II supports the undue

search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Each of Inventions I, III and V-VIII is separate and distinct from Invention IV as the polypeptides of Inventions I, III, V-VIII are structurally and biochemically different than the antibody of Invention IV. While the antibody of Group IV may bind to the polypeptide of Group I, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner. Inventions I,III, and V-VIII are therefore separate and distinct from Invention IV.

Invention II is separate and distinct from Group IV, as the claims of Inventions II are drawn to polynucleotides, while the claim of Group IV is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention IV would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Invention III is not related to any of Inventions I and V-VIII. The method of Group III is not limited to produce the polypeptide of Groups I or VI, nor is the peptide produced limited to be the same as that of Group I or Group VI. The polypeptides of Groups I and VI are not limited to made by the method of Group III. None of the methods of Groups V, VII or VIII recite use of the peptide produced by the method of Group III, and the method of Group III is directed to a

different result and recites different method steps than any of the methods of Groups V and VII-VIII. For these reasons, Group III is not related to any of Groups I or V-VIII.

Inventions I and VIII are not related to any of Inventions V-VII. The peptide of Group VI is a different structure than that of Group I, and is therefore a different product with different properties. Neither of the methods of Groups V and VII recite use of the polypeptide of Group I and the polypeptide of Group I is not limited to be one used in the method of either of Groups V or VII. The method of Group VIII does not recite use of the polypeptide of Group VI and recites different method steps and use of different materials than either of the methods of Groups V and VII. For these reasons, Groups I and VIII are not related to any of Groups V-VII.

Invention I is related to Invention VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ' 806.05(h)). In the instant case the polypeptide of Group I can be used in methods of making antibodies and in competition assays, therefore Groups I and VIII are separate and distinct.

Invention II is related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ' 806.05(h)). In the instant case the polynucleotide of Group II can be used in Southern blots, sequencing reactions, and hybridization assays, therefore Groups II and III are separate and distinct.

Inventions V is not related to either of Inventions VI or VII. The method of Invention V does not recite use of the polypeptide of Group VI and the polypeptide of Group VI is not limited

to be one used in the method of Group V. The methods of Groups V and VII are directed to different results and recite different method steps and use of different materials. For these reasons, neither of Groups VI or VII is related to Group V.

Invention VI is related to Invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ' 806.05(h)). In the instant case the polypeptide of Group VI can be used in methods of making antibodies and in competition assays, therefore Groups VI and VII are separate and distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper. In addition, because these inventions are distinct for the reasons given above and the search required for Groups II-VIII is not required for Group I, the search for Groups III-VIII is not required for Group II, a search for Groups II-III and V-VIII is not required for Group IV, a search for Groups I-IV and VI-VIII is not required for Group V, a search for Groups I-V and VII-VIII is not required for Group VI, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a

single polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The time period for compliance with the sequence rules, 37 CFR 1.821 - 1.825, is concurrent with the time period for reply to this office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply. Applicant is advised that any response to the restriction requirement without compliance with the sequence rules will be considered nonresponsive.

Conclusion

Claims 1-31 are restricted. The sequence rules must be complied with.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

Marjorie A. Moran
Examiner
Art Unit 1631

May 7, 2002

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER